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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,894	06/19/2001	Daniel J. O'Sullivan	110.01290101	1710

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EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/11/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,894

Applicant(s)

O'Sullivan

Examiner

Ware

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 13, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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Claims 1-40 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the microorganisms are required and recited in each of the claims, it is essential to the whole invention as recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or

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condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CAR § 1.807(b) which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

- (1) The name and address of the depository;
- (2) The name and address of the depositor;
- (3) The date of deposit;
- (4) The identity of the deposit and the accession number given by the depository;
- (5) The date of the viability test;
- (6) The procedures used to obtain a sample if the test is not done by the depository; and
- (7) A statement that the deposit is capable of reproduction.

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Applicant is also directed to 37 CAR § 1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:

- (1) The accession number for the deposit;
- (2) The date of the deposit;
- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
- (4) The name and address of the depository.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-8 are rendered vague and indefinite for the recitation of "having the characteristics of strain" since it is unclear whether or not the claimed isolates have all of the identifying characteristics of the recited strains, respectively. Thus, it is suggested to change the language to --having all of the identifying characteristics of strain--.

Claims 9-12 are rendered vague and indefinite for "a microbe". It is unclear whether "the microbe" is referring to "a Bifidobacterium" or not? Thus, the metes and bounds of the claims can not be determined. Further, it is unclear what exactly is being measured and what is being observed to decrease, for these same reasons. What is the difference between "a microbe", "a Bifidobacterium", and "a siderophore"? It is suggested to limit that claim 9 to claims 13 and 14 to properly describe "a microbe" per se. Such limitation is suggested to be in the form of

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Markush type language, such as -a prokaryotic microbe selected from the group consisting of- and then list each species of claim 14 within the group.

Claims 16-19 are rendered vague and indefinite since it is unclear what exactly is treating lactase deficiency, the siderophore or a Bifidobacterium? The metes and bounds of the claims cannot be determined. Explanation is suggested at this time and perhaps language inserted into claim to indicate the distinction of treatment.

Claims 20-26 are rendered vague and indefinite for whether or not the secretion of siderophore or Bifidobacterium which secretes is being measured or whether there is any significant correlation between the two for the method of establishing the flora. The metes and bounds of the claims are unclear.

Claim 27 is rendered vague and indefinite for failing to set forth clear and distinct process steps.

Claims 28 is rendered vague and indefinite for failing to clarify the comparison step. The method steps are vague as well as is the term "aberrant crypt foci in the colon". Explanation is requested at this time. Also the term "relative" is indefinite and should be deleted. Also "a lower number" is indefinite as to how low is the requirement for a decrease in colon cancer to be observed in order to meet the claim? The metes and bounds of the claim are unclear.

Claim 29 is rendered vague and indefinite for the recitation of "a microbe" for those reasons noted above.

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Claim 30 is rendered vague and indefinite since it unclear whether the siderophore is produced extracellularly or intra cellularly since it is secreted should it not be obtained extracellularly?

*D 34435
per in view* Claims 31 to 32, is unclear since it is uncertain how sterilization is to be carried out?
The metes and bounds of the claim are unclear. Removing all water is unclear as well.

Claim 33 is rendered confusing and wordy and the phrase "wherein the composition is sterile" should be deleted and the term "sterile" inserted before "composition" at line 1. Further, it is uncertain what else is in the composition beside the siderophore to make the claim a composition?

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per in view* Claims 34-39 are rendered vague and indefinite as to how the siderophore is obtained?
What process steps are used?

Claim 40 is rendered vague and indefinite for failing to set forth clear and distinct process steps for altering the expression of a siderophore.

2. Additionally, Applicant is advised that should claims 37 and 39 be found allowable, claims 36 and 38 will be objected to under 37 CAR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-9, 12-15, 20, 22-27, 29, 33-34 and 38-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Mutai et al (A).

Claims are drawn to isolated Bifidobacteria, method of inhibiting the growth of a microbe, method of establishing Bifidobacteria flora in an animal, method of preventing growth of microbes in food, composition for inhibiting the growth of a microbe, composition comprising a siderophore obtained from a Bifidobacterium, an isolated siderophore obtained from a Bifidobacterium, and method for inhibiting the growth of a microbe in a composition. Further, siderophore secreted by the Bifidobacteria are also claimed.

Mutai et al. teach isolated Bifidobacteria, method of inhibiting the growth of a microbe in the intestines of an animal, in food upon administration to an animal and thus, in a composition for an animal, composition for inhibiting growth of a microbe, etc. Note the abstract and column 1, lines 15-20 and column 2, lines 1-26.

The claims are identical to the cited disclosure, Mutai et al, and are therefore, considered to be anticipated by the teachings of the cited reference. The siderophore secreted from the Bifidobacteria is considered to be inherent to the teachings of the cited reference.

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 16, 18-19 and 28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rambaud et al, note the cited PTO-892 Form.

Claims are drawn to methods of treating a lactase deficiency and decreasing risk of colon cancer via the administering of a Bifidobacterium that secretes a siderophore.

Rambaud (aka. Rambaud et al) teaches methods of treating lactase deficiency and decreasing risk of colon cancer via administering a Bifidobacterium. Note the abstract and page 396, second column, all lines.

The claims are identical to the teachings of Rambaud and are, therefore, considered to be anticipated by the teachings of the cited reference. The siderophore is inherent to the teachings of Rambaud. However, in the alternative that there is some unidentified claim characteristic which provides for some difference between the methods claimed and those disclosed, then such difference is considered to be so slight as to render the claims obvious over the cited reference.

Claims 10-11, 17, 21, 30-32, 35-37 and 40 are rendered free of the prior art.

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The art-rejected claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.


The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware

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December 29, 2001